

Vascular Inflammation Risk

Identification & Reclassification

The Framingham Risk Score (FRS) is calculated by assigning points to an individual's age, gender, total cholesterol, HDL cholesterol, blood pressure, diabetes, family history, and smoking status. The individual scores are summed up to create a total score that corresponds to a percentage representing a person's 5-year risk of developing vascular disease.

SmartVascular Dx™ (SVDx) incorporates multiple biomarkers in combination with a proprietary algorithm to provide a comprehensive risk assessment that surpasses standard cholesterol tests including FRS.

SmartVascular Dx measures protein markers released by immune and endothelial cells which provide a window into the body's inflammatory response to vascular injury.

→ **42.7%**

of people who were considered at intermediate risk by a Framingham Risk Score were **CORRECTLY** reclassified by SmartVascular Dx^{1,2}

- SVDx reclassified 25.7% individuals with events, and 17% without events

In the Multi-Ethnic Study of Atherosclerosis (MESA) Study, SmartVascular Dx had improved sensitivity and specificity over the Framingham Risk Score for the classification of risk level associated with vascular damage.



Extensive Validation with 40,715 Total Patients

Studies Backed by National Institutes of Health (NIH)

Studies	Population Summary	Significance
Advance/Stanford	3,179 Adult Individuals Cases: 398 (post MI or UA) Controls: (age range: 60-72 years) no history of CAD	1. Proof of Concept 2. High sensitivity 3. Area under Curve (AUC) = 92% accurate in distinguishing between high- and low-risk individuals
Orentreich/Stanford	1,390 Adult Individuals (avg age: 62 years) Cases: 695 (MI or UA) Controls: Matched case-control	1. Ranked Biomarkers 2. Optimum Algorithm Size 3. Hazard Ratio (HR): 13x the risk of the healthy population
Personalized Medicine Research Project (PMRP) Marshfield Clinic	20,000 Members (age range: 40-80 years) Cases: 362 (MI or UA) Controls: 722 (disease-free at baseline and during the entire study)	→ SVDx Prognostic Algorithm Discovery Risk: Risk reclassification: 43-48% of 20,000 people moved into a more accurate risk category
Multiethnic Study of Atherosclerosis (MESA)	7,000 Individuals (age range: 45-85 years) Case Individuals: 179 (CAD) Controls: 495 (CAD free during study)	→ SVDx Verification and Transportability: Risk reclassification: 43% of 7,000 people moved into a more accurate risk category
SVDx Observational Study	9,146 Individuals Cases: n/a Controls: Patient is own control	SVDx Predictors of Risk in Diabetics and Predictors of High-Risk

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2. Solomon MD, Tirupsur A, Hytopoulos E, et al. (2013). Clinical utility of a novel coronary heart disease risk-assessment test to further classify intermediate-risk patients. *Clinical cardiology*, 36(10), 621–627. <https://doi.org/10.1002/clc.22185>

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